Recommended Template Format Sections

Title: COVERED ENTITY CHECKLIST TEMPLATE

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Introduction:

I. Purpose:

List all covered entities that may be affected by the Privacy Rule. The final regulations include new requirements relating to disclosures of protected health information.

The rule requires covered entities to prepare and make available a notice that informs individuals about uses and disclosures of protected health information that may be made by the covered entity and that informs the individual of their rights and covered entity's legal duties with respect to protected health information.

Covered Entities:

☐ Health Plan Includes any individual or group plan, private or governmental, that provides or pays for medical care.

☐ Health Care Clearinghouse is a public or private entity that processes health information received from another entity from non-standard into standard format, or vice versa.

☐ Health Care Provider is any person or organization that furnishes, bills or is paid for health care in the normal course of business. However, health care providers are covered by the rules only if they transmit electronic health information in connection with a standard transaction.

☐ Hybrid Entity is a single legal entity that is a covered entity, but the covered functions are not its primary functions.

☐ Affiliated Covered Entity is a separate covered entity associated with another covered entity. Legally separate covered entities may designate themselves as affiliate entities if they are all under common ownership or control

An entity that fits more than one definition must comply with the rules as they affect each of its functions, and may use or disclose information only as appropriate to the function for which the use or disclosure is made.

Covered Entities and Definitions: (Section 160.103)

See Covered Entity Checklist Pages 5 thru 8.

Responsibility of a Covered Entity: (Section 160.310)

Provide records and compliance reports as the HHS Secretary may determine to be necessary to enable the Secretary to ascertain whether the covered entity has complied or is complying with the applicable requirement and the applicable standard, requirements, and implementation specifications.

Cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of a covered entity to determine whether it is complying with the applicable requirements, and the standards, requirements, and implementation specifications.

Permit the Secretary access during normal business hours to its facilities, books, records, accounts, and other sources of information, including protected health information, and if the Secretary determines that the circumstances are urgent, then the covered entity must permit access at any time and without notice.

Covered Entity's Duties:

- Provide notice of privacy practices for protected health information. (Section 164.520)
- Notice of Privacy practices. A covered entity must inform and individual of the protected health information. The notice must contain the following statement as a header or otherwise be prominently displayed:

  "THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY."

- Implement specifications and document satisfaction assurance through a written contract or written agreement or arrangement with the business associate that meets the applicable requirement. (Section 164.504).

II. Assumptions and Pre-requisites:

- All covered entities are required to make policies and procedure changes to their current business practices based on the HIPAA requirements.
- Access current disclosure polices and procedures.
- Build awareness into the covered entity's organization about HIPAA.
- Develop policies and procedures on disclosure of what health information can be disclosed and for what purpose.
- Train all members of the workforce on policies and procedures with respect to protect health information.
- Develop an audit trail of health information disclosures as to whom, when, and for what purpose.
- Appoint a Privacy official who is responsible for development and implementation of privacy policy and procedures.
- Establish complaint process policy and procedures.
- Assign or designate at least one person or office responsible to receive complaints.
- Provide a uniform level of protection to all health information.
- Mandate safeguards for physical storage and maintenance.
- Obtain the individual's written consent for uses and disclosures to carry out treatment, payment, and health care operations.
- Obtain the individual's written authorization to use of their information for purposes other than treatment.
- Provide and apply appropriate sanctions against members of its workforce who fail to comply with the policies and procedures.
- When there is a change in the law that necessitates a policy and procedural change, it must be promptly revised, documented and implemented.
- Covered entities are required to keep all items that must be documented, including complaints, for at least six years from the date of creation.

III. Constraints:

- Funding
    - Budget
- Personnel
    - Insufficient
    - Unable to staff
    - Skills
- Training
    - Policy and Procedures development
    - Notice distribution
- Time
    - Meeting compliance requirement may be delayed due to time available or time allowed by the effective date of compliance on the Federal Register.

IV. Dependencies

- All covered entities workforce, as well as its business associate(s) and subcontractors must adhere and take responsibility for implementing the entity's policy and procedures to protect and secure the privacy of protected health information.
- All covered entities are required to comply by the HIPAA Rules and Regulations to protect and secure the privacy of protected health information.

V. Process:

- To implement policies and procedures to protect and secure the privacy of protected health information.

VI. Procedures:

- All covered entities should notify their business associate, partners and other affiliated entities though a written agreement or contract regarding their policy and procedures

on the privacy, security and confidential disclosure of protected health information.

- All covered entities must ensure that all business associates who receive protected health information from any covered entity only disclose or use the information only for the purpose agreed upon. This should also be covered though a third party entity.

All members of the workforce, as well as its business associate(s) and subcontractors must adhere and take responsibility for implementing the entity's policy and procedures regarding the release of protected health information.

VII. Guidelines:

- Provide clear definition of what a covered entity's functions and responsibility should be. (Section 160.310)

VIII. Accessibility:

- This template should be available to every entity that wants to determine if they fall in any of the categories of a covered entity.

IX. Compliance Criteria

- A covered entity must implement policies and procedures with respect to protected health information designed to comply with the HIPAA standards, implementation specifications, or other federal requirements. The policies and procedures must be reasonably designed to ensure such compliance, taking into account the size and the type of activities that relate to protected health information. This standard of implementing policies and procedures is not to be construed to permit or excuse an action that violates any other federal standard, implementation specification, or requirement. (Section 164.530(i)).

- A covered entity must change its policies and procedures as necessary and appropriate to comply with changes in the law, including the federal standards, implementation specifications, and requirements. (Section 164.530(I)).

Disclaimer

Information in this template is for general information only. It is not intended to provide legal advice to any entity. Please consult with your Legal Counsel before taking action based on information appearing on this template.

COVERED ENTITY CHECKLIST

A. ☐ **A Health Plan is an individual or group plan that provides, or pays the cost of, medical care.** Health Plans are further defined in lines 1 through 17 below. Specific *exclusions* are given in lines 1 through 6 below. *Be sure to check the exclusions on lines 1 through 6 before you make your decision.*

1. ☐ A group health plan [defined as an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300gg-91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that: (1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or (2) Is administered by an entity other than the employer that established and maintains the plan.

2. ☐ A health insurance issuer [defined as an insurance company, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

3. ☐ An HMO [defined as a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.]

4. ☐ Part A or Part B of the Medicare program under title XVIII of the Act.

5 ☐ The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, et seq.

6. ☐ An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).

7. ☐ An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.

8. ☐ An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers

9. ☐ The health care program for active military personnel under title 10 of the United States Code.

10. ☐ The veterans health care program under 38 U.S.C. Chapter 17.

11. ☐ The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)(as defined in 10 U.S.C. 1072(4)).

12. ☐ The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, et seq.

13. ☐ The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, et seq.

14. ☐ An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397, et seq.

15. ☐ The Medicare + Choice program under Part C of title XVIII of the Act, 42 U.S.C. 1395w-21 through 1395w-28.

16. ☐ A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals. [High-risk pools, as described in this rule, do not include any program established under state law solely to provide excepted benefits. For example, a state program established to provide workers' compensation coverage is not considered a high-risk pool under the rule.]

17. ☐ Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

B. ☐ **A Health Care Clearinghouse** is a public or private entity, including a billing service, re-pricing company, community health management information system or community health information system, and "value-added" networks and switches, that does either of the following functions:

1. Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing non standard format or containing nonstandard data into standard data transaction.

2. Received a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

C. ☐**A Health Care Provider** who transmits any health information in electronic form in connection with a transaction is a covered entity. Health care provider means a provider of services as defined in section 1861(u) of the Act, 42 U.S.C. 139x(u), a provider of medical or health services as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business. A provider of health care, services, or supplies related to the health of an individual. Health care includes, but is not limited to the following:

1. Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling service, assessment, or procedure with respect to the physical or mental condition, or functional status of an individual or that affects the structure or function of the body.

2. Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

3. The health care claims or equivalent encounter information transaction is the transmission of either of the following:

   A request to obtain payment, for health care, with the necessary accompanying information from a health care provider to a health plan. (Claim). or

   If there is no direct claim, because the reimbursement contract is based on mechanism other than charges or reimbursement rates for specific services, then the transaction is the transmission of encounter information for the purpose of reporting health care.

   Because the reimbursement contract is based on a mechanism other than charges or reimbursement rates for specific services, the transaction is the transmission of encounter information for the purpose of reporting health care (Encounter).

4. The eligibility for a health plan transaction is the transmission of either of the following:

   An inquiry from a health care provider to a health plan, or from one health plan to another health plan.

   To obtain any of the following information about a benefit plan for the enrollee:

   a. Eligibility to receive health care under the health plan.

   b. Coverage of health care under the health plan.

c. Benefits associated with the benefit plan.

Health Plan Exclusions: (1 thru 6)

1. ☐ *Excluding workers' compensation and automobile insurance carriers, other property and casualty insurers, and certain forms of limited benefits coverage, even when such arrangements provide coverage for health care services.*

2. ☐ *Excluding issuers of nursing home fixed-indemnity policies*

3. ☐ *Excluding any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits (my note: such as workers' comp) that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg-91(c)(1); and*

4. ☐ *Excluding any government-funded program (other than one listed in paragraph (1)(i)-(xvi) of this definition) whose principal purpose is other than providing, or paying the cost of, health care [but which do incidentally provide such services. For example, programs such as the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) and the Food Stamp Program, which provide or pay for nutritional services, are not considered to be health plans.*

5. ☐ *Excluding any government-funded program (other than one listed in paragraph (1)(i)-(xvi)of this definition) whose principal activity is (1) The direct provision of health care to persons; or (2) The making of grants to fund the direct provision of health care to persons. Examples include the Ryan White Comprehensive AIDS Resources Emergency Act, government funded health centers and immunization programs. (Note: Some of these may meet the rule's definition of health care provider.)*

6. ***NOTE: COUNTIES, PAY ATTENTION TO THIS ONE:*** *Excluding agencies that determine eligibility for or enrollment in a health plan that is a government program providing public benefits (such as Medicaid or SCHIP) when that agency is not the agency that administers the program. For example, an agency that is not otherwise a covered entity, such as a local welfare agency, is not considered to be a covered entity because it determines eligibility or enrollment or collects enrollment information as authorized by law. We also do not consider the agency to be a business associate when conducting these functions.*

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